

IV. AMENDMENTS TO THE DRAWINGS

--- Replacement and annotated mark-up drawing sheets for amended figures showing the amended figures, if any, are attached at the Appendix hereto. Each figure is in compliance with 37 C.F.R. § 1.84. An explanation of the changes, if any, is set forth below in this “Amendments to the Drawings” section. Replacement drawing sheets are identified in the top margin as “Replacement Sheet.” Any replacement drawing sheet including amended figures includes all of the figures appearing on the immediate prior version of the sheet. Any annotated drawing sheets, if the same are required by the Examiner, are identified in the top margin as “Annotated Marked-Up Drawings.” Any deleted figure is noted by an instruction to delete the figure. Any corresponding amendment to the specification necessary to be made because of an amendment to the drawings in this section is made in the corresponding “Amendments to Specification” section.

- THE DRAWINGS OF THE PATENT IS HEREBY AMENDED AS SET FORTH BELOW:
 - *No Drawings are Present in this Application*
 - *Attachments: None*

V. REMARKS/ARGUMENTS

- STATUS OF THE CLAIMS

Claims 1, 5, 14, 15, are pending in this application. There are currently no amendments.

- REJECTIONS

REJECTION UNDER 35 U.S.C. §103(a)

Applicants herein address the Examiner's 103(a) rejections with respect to the claims as set forth in the Examiner's Office Action.

- Examiner's Position

Claims 1, 5, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Western Communion Hosts" in view of Salza (U.S. Patent No. 3,836,680) for essentially the same reasons stated in the June 9th, 2009 Non-Final Office action.

It is the Examiner's opinion the pending claims recite the wafer and not the method/process of producing the wafer. The Examiner, therefore, alleges that the method steps included in the product claims would not impart any patentable distinction. The Examiner asserts that Salza reference is not relied upon for the use of an emulsifier but instead Salza is relied upon as a teaching of substituting wheat flour ... with a mixture of ungelatinized and pre-gelatinized wheat starch in order to produce a gluten-free product suitable for gluten-intolerant individuals.

The Examiner relies on and alleges that "Western Communion Hosts" teaches the traditional preparation of communion alter bread and as teaching the recognitions of the problem encounter by gluten intolerant and the need for recipe containing alternate ingredients. The Examiner alleges one of ordinary skill in the art would have been motivated to use modify "Western Communion Hosts" to and use the teaches of Salza to produce a communion host with ungelatinized and pre-gelatinized wheat starch instead of wheat flour to satisfy the strict religious

requirements and medical needs. The Examiner further alleges that Salza discloses proportions of water and starch (Col. 2 lines 18-20) and that it would have been obvious to one of ordinary skill to rehydrate prior to consumption the dried product disclosed by Salza. Finally the Examiner alleges Salza in claim 1, discloses the formation of a homogeneous mixture of water, pre-gelatinized and non-gelatinized starch (Col. 2 lines 60-67). Although Salza does not does not describe the proportion of pre-gelatinized starch to non-gelatinized starch, the Examiner contends that one would have been motivated to use proportions that yielded similar characteristics to the gluten-containing wafers.

- Applicants' Response

Applicant thanks the Examiner for the thoughtful comments but respectfully traverses the Examiner's rejection of claims 1, 5, 14, and 15 over "Western Communion Hosts" in view of Salza.

With respect to instant independent claim 1, the limitations require, in part:

A low-gluten wafer pre-cooked mixture consisting of:
about 50% of a mixture of wheat starch and pre-gelatinized wheat starch
to form a first homogeneous mixture combined with 50% of water, said
water being at a temperature of between about 100 degrees Fahrenheit and
about 150 degrees Fahrenheit to form a second homogeneous mixture,
wherein said wheat starch and said pre-gelatinized wheat starch
are substantially equal in amount.

This is patently distinct from the combined teachings of Salza and "Western Communion Hosts" since the combined teachings at least require the wafer composition to include an emulsifier preferably a monoglyceride – a correlative component as is any non-wheat component and excluded by the limitations of instant claim 1. "Western Communion Hosts" alternatively substitutes non-wheat protein to solve the fundamental problem of paste consistency. Consequently the combined teachings of Salza and "Western Communion Hosts" remain patently distinct from the instant claim.

In regard to the Applicant's assertions that Salza teaches the necessity of an emulsifier, the Examiner points out that "Salza is not relied upon as a teaching of emulsifiers.." but Salza is

instead "...relied upon as a teaching of substituting wheat flour as a traditional pasta ingredient with a mixture of ungelatinized and pre-gelatinized wheat starch in order to produce [a] gluten-free product..."(p3 lines 11-13 of the Action).

The Applicant strongly disagrees. Salza does not (with emphasis) teach the substitution of a mixture of ungelatinized and pregelatinized wheat starch but instead teaches the substitution with a mixture of ungelatinized, pregelatinized wheat starch and an emulsifier/monoglyceride. Salza specifically describes the emulsifier. Salza even teaches why an emulsifier is needed – "...to promote dispersion of these two components [the ungelatinized and gelatinized starch], in the mixture, small amounts of monoglycerides of the alimentary fatty acids of C₁₄ to C₁₈ are added as emulsifiers..."(Salza C1 lines 51-53).

The criticality of the combined use of an emulsifier, unglutinized and preglutinized is further taught in the description of the two-stage and single stage embodiments of column 1 and 2, and also taught in the examples of the second to last and last paragraphs of column 2 and in the claims. In total, Salza refers the emulsifier/monglyceride 15 times in the 1.5 page patent and does not include a single embodiment or suggestion wherein unglutinized and preglutinized wheat starch may be used as a protein substitute without an emulsifier. It is clear that the emulsifier is as much a part of the Salza invention as the starches. To an ordinary artisan, the Salza invention as described by Salza is not operable without the emulsifier.

Furthermore, one of ordinary skill in the art would understand that Salza does not provide a solution to the gluten intolerance problem recognized by "Western Communion Hosts" because the alternative ingredients taught by Salza, and required by the Salza teachings must contain an emulsifier. One of ordinary skill in the art would immediately realize that the alternative of Salza is unacceptable and of no advantage over the alternatives suggested by "Western Communion Hosts."

Accordingly for one of ordinary skill in the art, and contrary to the Examiner's opinion, the artisan would not have been "...motivated to modify Western Communion Hosts in view of Salza and to substitute wheat flour mixture with ungelatinized and pre-gelatinized wheat starch..." (p4 lines 4-6 of the Action) because there is no suggestion of success. Instead one of ordinary skill would unambiguously understand from the Salza's teachings and Salza's lack of

alternative embodiments that the combination of pregelatinized and ungelatinized wheat starch requires an emulsifier.

The Examiner's allegations (1st line of p4 and 1st paragraph of p5 of the Action) that "Salza discloses forming a homogeneous mixture of water, pre-glutinizied and non-glutinizied starch." The Examiner cites Claim 1 of Salza. However in that reference Salza explicitly requires a composition of "gelatinized starch, ungelatinized starch and an emulsifier..." The Examiners further alleges of that one of ordinary skill in the art would have been motivated to vary the proportions of pregelatinized starch to the non-gelatinized starch in order to produce product having the same or similar characteristics in order to produce the product having the same or similar characteristics to the gluten-containing counterpart." But to the contrary, Salza teaches that in order to combine the pregelatinized starch and the non-gelatinized starch you need the emulsifier.

Instant Claim 1 is patently distinct from the combination of Salza and "Western Communion Hosts" because the composition and conditions unexpectedly discovered by the applicant are neither taught nor suggested the references separately or together. Applicant also asserts that the Examiner's use of the combination of Salza and "Western Communion Hosts" is improper. "...[T]he claimed combination cannot change the principle of the primary reference or render the reference inoperable for its intended purpose." (MPEP 2145 III last paragraph) By relying on Salza "as a teaching of substituting of wheat flour" alone without the use of the emulsifier as taught and required, the Examiner renders the Salza reference inoperable.

Accordingly, Applicants assert that the teachings of "Western Communion Hosts" in view of the Salza reference do not form a *prima facie* case of obviousness, as there would be no motivation for combination since Salza provides no suggestion of success and is inoperable without the emulsifier. Therefore, Applicants assert that rejection of the instant Claim 1 is improper under 35 U.S.C. §103(a), and respectfully request withdrawal of the rejection.

Instant dependent claims 4, 14 and 15 depend directly or indirectly from instant independent claim 1. The Applicants assert that instant independent claim 1 is non-obvious. In accordance with MPEP 2143.03, if an independent claim is non-obvious under 35 U.S.C. §103,

then any claim depending therefrom is non-obvious (*In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) 90 and the respective rejections should be rescinded.

CONCLUSION TO REMARKS

Applicants assert that this response is fully responsive to the Examiner's Office Action dated June 8, 2010. In view of the arguments presented, Applicants respectfully seek early allowance of the pending claims.

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Respectfully Submitted,



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VI. APPENDIX

- *No Appendix Included in this Response.*